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09/965,561	09/25/2001	J. Gregor Sutcliffe	TSRI 401.0D5	3947

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EXAMINER

KENEDY, ANDREW A

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 03/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/965,561

**Applicant(s)**

SUTCLIFFE ET AL.

**Examiner**

Andrew A. Kenedy

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 38-43 is/are pending in the application.
- 4a) Of the above claim(s) 41-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 38-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 38-43 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 September 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 09964597,08152482.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_.

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## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of Group I (claims 38-40) in the response dated July 28, 2003, is acknowledged. Claims 41-43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

### ***Oath/Declaration***

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02. The oath or declaration is defective because:

This application presents a claim for subject matter not originally claimed or embraced in the statement of the invention of the parent applications from which the instant application derives, as follows: The instant application is claimed as a division of parent application 09/316349 (issued patent No. 6309834), which is claimed as a division of parent application 09/035190 (issued patent No. 6030784). Parent application 09/316349 does not disclose transformation of a database entry, determining index sequences, or graphically displaying the length of a correlate sequence in relation to an index sequence. Furthermore, the terms "index sequence(s)" and "correlate sequence(s)" do not appear within that application. Parent application 09/035190 does not disclose transformation of a database entry, choosing a source

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sequence from a database for transformation, determining index sequences, determining correlate sequences, or graphically displaying the length of a correlate sequence in relation to an index sequence. Furthermore, the terms "index sequence(s)" and "correlate sequence(s)" do not appear anywhere within that application. Therefore, applicants' instant application may qualify as a continuation-in-part, but not as a divisional as claimed.

A supplemental oath or declaration is required under 37 CFR 1.67. The new oath or declaration must properly identify the application of which it is to form a part, preferably by application number and filing date in the body of the oath or declaration. See MPEP §§ 602.01 and 602.02.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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**Claims 38-40 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1, 11 and 12 of U.S. Patent No. 6309834 in view of Guilfoyle et al. (US 6280948 B1).**

With respect to Claim 38, U.S. Patent No. 6309834 claims a method of recognizing sequence identities and similarities between the sequence of 3'-ends of mRNA molecules present in a sample and a database of sequences. Claim 1(m) requires determining corresponding nucleotide sequences (determining a correlate sequence within a source sequence) from a database of nucleotide sequences (choosing a source sequence from a polynucleotide database entry), said corresponding nucleotide sequences being delimited by a endonuclease recognition site and the poly(A) tail (locating a poly(A) tail sequence, locating an endonuclease recognition site, and determining a correlate sequence within the source sequence including the sequence bounded by the poly(A) tail and the endonuclease recognition site and including at least part of the endonuclease site); and comparing the sequence of the cloned cDNA to the corresponding nucleotide sequences, thereby recognizing sequence identities and similarities between the sequence of 3'-ends of mRNA molecules present in a sample and a database of sequences (determining the length of the correlate sequence, the location and sequence of the poly(A) tail, the location and sequence of the endonuclease recognition site, and the length of the correlate sequence in relation to the source sequence).

While U.S. Patent No. 6309834 does not teach storing the above information, it would have been obvious to one of ordinary skill in the art to store the above results in a database to

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produce a transformed sequence database entry since the above methods are performed by retrieving and manipulating sequence information stored in computerized databases.

U.S. Patent No. 6309834 also does not teach the limitation of determining an index sequence consisting of about 2 to about 6 nucleotides adjacent to the endonuclease recognition site.

Guilfoyle et al. teaches a method of indexing sequences -- including polynucleotides representing the 3'-end of an mRNA having a poly(A) tail sequence -- by using short index sequences, preferably 3 to 5 nucleotides long, adjacent to endonuclease recognition sites of the polynucleotide sequences (see at least the abstract; Fig. 1-5; col. 5, lines 39-63; col. 12, lines 60-64; and Claims 1-3).

It would have been obvious for one of ordinary skill in the art to combine the teachings of Guilfoyle et al. with U.S. Patent No. 6309834, since Guilfoyle et al. teaches that determination and utilization of an indexing sequence adjacent to an endonuclease recognition site at the end of a nucleotide sequence representing the 3'-end of an mRNA allows for generating "fingerprints" that can be "useful for creating and searching EST databases" and in RNA profiling (see at least col. 15, line 20 -- col. 16, line 19; and col. 12, lines 60-64).

With respect to Claim 39, U.S. Patent No. 6309834 teaches comparing and displaying the lengths of the above corresponding nucleotide sequences in a two dimensional graphical display, thereby making it obvious to also display the length of the corresponding nucleotide sequence (the correlate sequence) in relation to the index sequence (see at least Claim 4(q)).

With respect to Claim 40, U.S. Patent No. 6309834 teaches that the restriction endonuclease can be Msp1, Taq1, or HinP1I (see at least Claims 11 and 12).

**Claims 38-40 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1 and 3 of U.S. Patent No. 6633818 in view of Guilfoyle et al. (US 6280948 B1).**

With respect to Claim 38, U.S. Patent No. 6633818 claims a method for simultaneous comparison of sequences of mRNA's in an mRNA population to data stored on a computer readable medium. Claim 1(l) requires comparing the data stored on the computer readable medium to indicate sequence relationship matches of between nucleotide sequences (choosing a source sequence from a polynucleotide database entry). Claim 1(a)-(b) requires polynucleotide sequences created using a primer having from 7 to 40 T residues (a poly(A) tail sequence) and a primer containing neighboring endonuclease recognition site sequence while Claim 1(j) requires determining the sequence and the length of each polynucleotide sequence representing a 3'-end of mRNA (locating a poly(A) tail sequence, locating an endonuclease recognition site, determining a correlate sequence within the source sequence including the sequence bounded by the poly(A) tail and the endonuclease recognition site and including at least part of the endonuclease site, and determining the length of the correlate sequence in relation to the source sequence). Claim 1(k) requires storing the above sequence and length results (storing information concerning the location and sequence of the poly(A) tail, the location and sequence

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of the endonuclease recognition site, and the length of the correlate sequence in relation to the source sequence, thereby producing a transformed database entry).

U.S. Patent No. 6633818 also does not teach the limitation of determining an index sequence consisting of about 2 to about 6 nucleotides adjacent to the endonuclease recognition site.

Guilfoyle et al. teaches a method of indexing sequences -- including polynucleotides representing the 3'-end of an mRNA having a poly(A) tail sequence -- by using short index sequences, preferably 3 to 5 nucleotides long, adjacent to endonuclease recognition sites of the polynucleotide sequences (see at least the abstract; Fig. 1-5; col. 5, lines 39-63; col. 12, lines 60-64; and Claims 1-3).

It would have been obvious for one of ordinary skill in the art to combine the teachings of Guilfoyle et al. with U.S. Patent No. 6633818, since Guilfoyle et al. teaches that determination and utilization of an index sequence adjacent to an endonuclease recognition site at the end of a nucleotide sequence representing the 3'-end of an mRNA allows for generating "fingerprints" that can be "useful for creating and searching EST databases" and in RNA profiling (see at least col. 15, line 20 -- col. 16, line 19; and col. 12, lines 60-64).

With respect to Claim 39, while U.S. Patent No. 6633818 does not explicitly teach displaying graphically the length of sequences in relation to each other. However, since the above method involves storing and comparing the sequence data and results on a computer (see at least Claim 1), it would have been obvious to one of ordinary skill in the art to display



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graphically the length of the correlate sequence in relation to the index sequence on the computer's graphical display monitor.

With respect to Claim 40, U.S. Patent No. 6633818 teaches that the restriction endonuclease can be MspI, TaqI, or HinPII (see at least col. 7, lines 48-51).

***Claim Rejections - 35 USC § 112***

**Claim 38 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

It appears that the phrase "the first recognition site" refers to the previously mentioned "poly(A) tail sequence", however, this it is not clear since the poly(A) tail sequence is not indicated to be a recognition site. Applicant needs to clarify this within the claim.

The phrase "consisting of about two to about six nucleotides" is indefinite as to the number of nucleotides encompassed since the term "about" does not precisely define the metes and bounds of the limitation, thereby rendering the scope of the claim uncertain.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**Claims 38 and 39 are rejected under 35 U.S.C. 102(e) as being anticipated by**

**Kinzler et al. (US 6383743 B1).**

As discussed previously in regard to the oath/declaration, Claims 38 and 39 of applicants' instant application are not fully supported by the disclosure of either of parent applications 09/316349 or 09/035190 and therefore do not receive the benefit of priority. Therefore, Kinzler et al., relied upon in this rejection, is valid prior art under 102(b) against the instant claims.

With respect to Claim 38, Kinzler et al. teaches a method of comparing polynucleotide sequences with known polynucleotide sequences in a database (choosing a source sequence from a polynucleotide sequence database entry) (see at least Claim 18); wherein the sequences to be compared represent the 3-ends of mRNA's and span the length from the poly(A) tail to the closest endonuclease restriction site (locating a poly(A) tail sequence within the source sequence; locating the nearest endonuclease recognition site sequence within the source sequence) (see at least Fig. 1A; col. 5, lines 5-11; and Claim 18); determining a tag sequence as short as 6 to 7 nucleotides (determining an index sequence consisting of about 2 to about 6 nucleotides) adjacent to the endonuclease recognition site (see at least Fig. 1A-B; col. 2, lines 59-64; and col. 4, lines 52-58); matching a first nucleotide sequence located at a defined position 3' of the 3'-most endonuclease cleavage site within an mRNA to a second nucleotide sequence in a database (determining a correlate sequence within the source sequence, the correlate sequence including

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the sequence bounded by the poly(A) tail sequence and the endonuclease recognition site) (see at least Claim 18); determining that the second nucleotide sequence is located at a defined position within the respective mRNA or cDNA molecule and identifying the first nucleotide sequence with the sequence in the database (determining the length of the correlate sequence) (see at least Claim 18); and storing the above information in a computerized data storage system (storing the information concerning the location and sequence of the poly(A) tail, the location and sequence of the endonuclease recognition site, and the length of the correlate sequence in relation to the source sequence, thereby producing a transformed database entry) (see at least col. 10, lines 50-67).

With respect to Claim 39, Kinzler et al. teaches that the sequence information can be output in graphic form on a computer output device (displaying graphically the length of the correlate sequence in relation to the index sequence) (see at least col. 10, lines 50-62).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 38-40 rejected under 35 U.S.C. 103(a) as being unpatentable over Sutcliffe et al. (US 6633818 B1) in view of Guilfoyle et al. (US 6280948 B1).**

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As discussed previously in regard to the oath/declaration, Claims 38-40 of applicants' instant application are not fully supported by the disclosure of either of parent applications 09/316349 or 09/035190 and therefore do not receive the benefit of priority. Therefore, Sutcliffe et al. and Guilfoyle et al., relied upon in this rejection, are valid prior art under 103(a) against the instant claims.

With respect to Claim 38, Sutcliffe et al. (US 6633818 B1) teaches a method for simultaneous comparison of sequences of mRNA's in an mRNA population to data stored on a computer readable medium wherein Claim 1(l) requires comparing the data stored on the computer readable medium to indicate sequence relationship matches of between nucleotide sequences (choosing a source sequence from a polynucleotide database entry). Claim 1(a)-(b) requires polynucleotide sequences created using a primer having from 7 to 40 T residues (a poly(A) tail sequence) and a primer containing neighboring endonuclease recognition site sequence while Claim 1(j) requires determining the sequence and the length of each polynucleotide sequence representing a 3'-end of mRNA (locating a poly(A) tail sequence, locating an endonuclease recognition site, determining a correlate sequence within the source sequence including the sequence bounded by the poly(A) tail and the endonuclease recognition site and including at least part of the endonuclease site, and determining the length of the correlate sequence in relation to the source sequence). Claim 1(k) requires storing the above sequence and length results (storing information concerning the location and sequence of the poly(A) tail, the location and sequence of the endonuclease recognition site, and the length of the

correlate sequence in relation to the source sequence, thereby producing a transformed database entry).

Sutcliffe et al. also does not teach the limitation of determining an index sequence consisting of about 2 to about 6 nucleotides adjacent to the endonuclease recognition site.

Guilfoyle et al. teaches a method of indexing sequences – including polynucleotides representing the 3'-end of an mRNA having a poly(A) tail sequence -- by using short indexing sequences, preferably 3 to 5 nucleotides long, adjacent to endonuclease recognition sites of the polynucleotide sequences (see at least the abstract; Fig. 1-5; col. 5, lines 39-63; col. 12, lines 60-64; and Claims 1-3).

It would have been obvious for one of ordinary skill in the art to combine the teachings of Guilfoyle et al. with Sutcliffe et al., since Guilfoyle et al. teaches that determination and utilization of an index sequence adjacent to an endonuclease recognition site at the end of a nucleotide sequence representing the 3'-end of an mRNA allows for generating "fingerprints" that can be "useful for creating and searching EST databases" and in RNA profiling (see at least col. 15, line 20 – col. 16, line 19; and col. 12, lines 60-64).

With respect to Claim 39, while Sutcliffe et al. does not explicitly teach displaying graphically the length of sequences in relation to each other. However, since the above method involves storing and comparing the sequence data and results on a computer (see at least Claim 1), it would have been obvious to one of ordinary skill in the art to display graphically the length of the correlate sequence in relation to the index sequence on the computer's graphical display monitor.

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With respect to Claim 40, Sutcliffe et al. teaches that the restriction endonuclease can be MspI, TaqI, or HinfI (see at least col. 7, lines 48-51).

**Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kinzler et al. (US 6383743 B1) in view of Roberts et al. (*Nucleic Acids Research*, 1998).**

As discussed previously in regard to the oath/declaration, Claims 40 of applicants' instant application is not fully supported by the disclosure of either of parent applications 09/316349 or 09/035190 and therefore does not receive the benefit of priority. Therefore, Kinzler et al. and Roberts et al., relied upon in this rejection, are valid prior art under 103(a) against the instant claims.

With respect to Claim 40, Kinzler et al. teaches that the endonuclease recognition site can be a Type II endonuclease site, but does not explicitly mention MspI, TaqI and HinfI. Roberts et al. teaches that Type II endonucleases are a class/family of endonucleases that includes MspI, TaqI and HinfI (see pg. 344 and 348). It would have been obvious for one of ordinary skill in the art to combine the teachings of Roberts et al. with the method of Kinzler et al., since Kinzler et al. does not provide a listing of Type II endonucleases, while Roberts et al. does.

***Made of Record***

Prior Art made of record which discloses various aspects of applicant's instant invention but was not relied upon:

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Applicants' IDS documents: Adams et al. (exhibit 10) teaches comparing the sequences and lengths of ESTs (sequences representing the 3'-end of mRNA) using databases; Adams et al. (exhibit 11) teaches comparing the sequences and lengths of ESTs using databases; Liang et al. (exhibit 15 ) teaches the sequencing and comparison of nucleotide sequences containing poly(A) tail sequence representing the 3'-end of mRNAs.

***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew A. Kenedy whose telephone number is (571)-272-0574. The examiner can normally be reached on Monday-Friday 9:00am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571)-272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.A.K. March 15, 2004

*Marianne P. Allen*  
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PRIMARY EXAMINER  
3/12/04  
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